Case Series Drug Analysis Print Name: FOI 21/590 Anthrax Vaccine

Report Run Date:	29-Jun-2021
Data Lock Date:	08-Apr-2021 19:00:04
Earliest Reaction Date:	14-Jan-1992
MedDRA Version:	MedDRA 23.1
FOI 21/590 Anthrax Vaccine:	All UK suspected, spontaneous adverse drug reactions reports associated with the Anthrax vaccine until 08/04/2021

Report Run Date: 29-Jun-2021	Data Lock Date: 08-Apr-2021 19:00:04		
Earliest Reaction Date: 14-Jan-1992	MedDRA Version: MedDRA 23.1		
Reaction Name		Total	Fatal
Blood disorders			
Lymphatic system disorders NEC			
Lymphadenopathy		3	0
Blood disorders SOC TOTAL		3	0

Report Run Date: 29-Jun-2021 Earliest Reaction Date: 14-Jan-1992	Data Lock Date: 08-Apr-2021 19:00 MedDRA Version: MedDRA 23.1	0:04	
Reaction Name		Total	Fatal
Cardiac disorders			
Cardiac signs and symptoms NEC			
Palpitations		1	0
Cardiac disorders SOC TOTAL		1	0

Name: FOI 21/590 Anthrax Vaccine

Report Run Date: 29-Jun-2021 Data Lock Date: 08-Apr-2021 19:00:04 MedDRA Version: MedDRA 23.1 Earliest Reaction Date: 14-Jan-1992 Reaction Name Total Fatal Eye disorders Ocular disorders NEC Periorbital swelling 0 1 Visual disorders NEC Vision blurred 0 1 Eye disorders SOC TOTAL 2 0

Name: FOI 21/590 Anthrax Vaccine

Report Run Date: 29-Jun-2021 Earliest Reaction Date: 14-Jan-1992

Reaction Name	Total	Fatal
Gastrointestinal disorders		
Diarrhoea (excl infective)		
Diarrhoea	6	0
Gastrointestinal and abdominal pains (excl oral and throat)		
Abdominal pain	1	0
Abdominal pain upper	1	0
Gastrointestinal atonic and hypomotility disorders NEC		
Constipation	1	0
Nausea and vomiting symptoms		
Nausea	9	0
Vomiting	8	0
Gastrointestinal disorders SOC TOTAL	26	0

Name: FOI 21/590 Anthrax Vaccine

Report Run Date: 29-Jun-2021 Earliest Reaction Date: 14-Jan-1992

Reaction Name	Total	Fatal
General disorders		
Asthenic conditions		
Asthenia	5	0
Fatigue	10	0
Malaise	12	0
Febrile disorders		
Pyrexia	12	0
Feelings and sensations NEC		
Chills	1	0
Feeling cold	1	0
Thirst	2	0
General signs and symptoms NEC		
Illness	2	0
Influenza like illness	13	0
Local reaction	4	0
Peripheral swelling	9	0
Swelling	8	0
Injection site reactions		
Injection site erythema	1	0
Injection site inflammation	5	0
Injection site pain	15	0
Injection site reaction	6	0
Injection site swelling	1	0
Injection site warmth	1	0
Pain and discomfort NEC		
Axillary pain	1	0
Chest discomfort	1	0
Pain	6	0
Tenderness	1	0
Vaccination site reactions		
Vaccination site inflammation	1	0
Vaccination site pain	1	0
Vaccination site swelling	2	0
General disorders SOC TOTAL	121	0

Report Run Date: 29-Jun-2021	Data Lock Date: 08-Apr-2021 19:00	0:04	
Earliest Reaction Date: 14-Jan-1992	MedDRA Version: MedDRA 23.1		
Reaction Name		Total	Fatal
Immune system disorders			
Allergic conditions NEC			
Hypersensitivity		2	0
Anaphylactic and anaphylactoid responses			
Anaphylactic reaction		1	0
Immune system disorders SOC TOTAL		3	0

Name: FOI 21/590 Anthrax Vaccine

Report Run Date: 29-Jun-2021Data Lock Date: 08-Apr-2021 19:00:04Earliest Reaction Date: 14-Jan-1992MedDRA Version: MedDRA 23.1

Earliest Reaction Date: 14-Jan-1992	Meduka version. Meduka 23.1		
Reaction Name		Total	Fatal
Infections			
Infections NEC			
Abscess		1	0
Urinary tract infections			
Urethritis		1	0
Infections SOC TOTAL		2	0

Name: FOI 21/590 Anthrax Vaccine

 Report Run Date: 29-Jun-2021
 Data Lock Date: 08-Apr-2021 19:00:04

 Earliest Reaction Date: 14-Jan-1992
 MedDRA Version: MedDRA 23.1

 Reaction Name
 Total
 Fatal

 Injuries
 Injuries NEC
 Injuries NEC

 Fall
 1
 0

 Injuries SOC TOTAL
 1
 0

Name: FOI 21/590 Anthrax Vaccine

Report Run Date: 29-Jun-2021 Earliest Reaction Date: 14-Jan-1992

Reaction Name	Total	Fatal
Investigations		
Coagulation and bleeding analyses		
International normalised ratio increased	1	0
Neurologic diagnostic procedures		
Nerve conduction studies abnormal	1	0
Urinalysis NEC		
Blood urine present	1	0
Investigations SOC TOTAL	3	0

Name: FOI 21/590 Anthrax Vaccine

Report Run Date: 29-Jun-2021 Earliest Reaction Date: 14-Jan-1992

Reaction Name	Total	Fatal
Muscle & tissue disorders		
Joint related signs and symptoms		
Arthralgia	10	0
Muscle pains		
Myalgia	13	0
Muscle related signs and symptoms NEC		
Muscle disorder	1	0
Muscle spasms	4	0
Musculoskeletal and connective tissue conditions NEC		
Musculoskeletal stiffness	2	0
Musculoskeletal and connective tissue pain and discomfort		
Back pain	2	0
Pain in extremity	14	0
Myopathies		
Rhabdomyolysis	1	0
Spondyloarthropathies		
Arthritis reactive	2	0
Muscle & tissue disorders SOC TOTAL	49	0

Name: FOI 21/590 Anthrax Vaccine

Report Run Date: 29-Jun-2021 Earliest Reaction Date: 14-Jan-1992

Reaction Name	Total	Fatal
Nervous system disorders		
Abnormal reflexes		
Hyperreflexia	1	0
Coordination and balance disturbances		
Coordination abnormal	1	0
Disturbances in consciousness NEC		
Lethargy	5	0
Syncope	1	0
Dyskinesias and movement disorders NEC		
Clumsiness	2	0
Headaches NEC		
Headache	11	0
Mental impairment (excl dementia and memory loss)		
Disturbance in attention	3	0
Mononeuropathies		
Meralgia paraesthetica	1	0
Narcolepsy and hypersomnia		
Hypersomnia	1	0
Neurologic visual problems NEC		
Tunnel vision	1	0
Neurological signs and symptoms NEC		
Dizziness	6	0
Paraesthesias and dysaesthesias		
Anaesthesia	1	0
Hypoaesthesia	3	0
Paraesthesia	5	C
Peripheral neuropathies NEC		
Neuropathy peripheral	2	C
Spinal cord and nerve root disorders NEC		
Radiculopathy	1	C
Tremor (excl congenital)		
Tremor	2	C
Nervous system disorders SOC TOTAL	47	0

Report Run Date: 29-Jun-2021	Data Lock Date: 08-Apr-2021 19:00:04		
Earliest Reaction Date: 14-Jan-1992	MedDRA Version: MedDRA 23.1		
Reaction Name		Total	Fatal
Pregnancy conditions			
Abortions spontaneous			
Abortion spontaneous		1	0
Pregnancy conditions SOC TOTAL		1	0

Name: FOI 21/590 Anthrax Vaccine

Report Run Date: 29-Jun-2021 Earliest Reaction Date: 14-Jan-1992

Reaction Name	Total	Fatal
Psychiatric disorders		
Anxiety symptoms		
Anxiety	2	0
Confusion and disorientation		
Disorientation	1	C
Emotional and mood disturbances NEC		
Emotional disorder	1	C
Irritability	1	0
Psychiatric disorders SOC TOTAL	5	

Name: FOI 21/590 Anthrax Vaccine

Report Run Date: 29-Jun-2021 Earliest Reaction Date: 14-Jan-1992

Reaction Name	Total	Fatal
Renal & urinary disorders		
Bladder and urethral symptoms		
Dysuria	1	0
Pollakiuria	1	0
Urinary tract signs and symptoms NEC		
Renal pain	3	0
Renal & urinary disorders SOC TOTAL	5	0

Name: FOI 21/590 Anthrax Vaccine

Report Run Date: 29-Jun-2021 Data Lock Date: 08-Apr-2021 19:00:04 MedDRA Version: MedDRA 23.1 Earliest Reaction Date: 14-Jan-1992 Reaction Name Total Fatal Respiratory disorders Breathing abnormalities Dysphoea 0 1 Upper respiratory tract signs and symptoms Oropharyngeal pain 0 1 **Respiratory disorders SOC TOTAL** 2 0

Name: FOI 21/590 Anthrax Vaccine

Report Run Date: 29-Jun-2021 Earliest Reaction Date: 14-Jan-1992

Reaction Name	Total	Fatal
Skin disorders		
Angioedemas		
Angioedema	1	0
Apocrine and eccrine gland disorders		
Cold sweat	1	0
Hyperhidrosis	4	0
Night sweats	2	0
Dermal and epidermal conditions NEC		
Skin discolouration	1	0
Skin induration	1	0
Dermatitis and eczema		
Eczema	1	0
Erythemas		
Erythema	3	0
Rashes, eruptions and exanthems NEC		
Rash	1	0
Urticarias		
Urticaria	6	0
Skin disorders SOC TOTAL	21	0

Name: FOI 21/590 Anthrax Vaccine

Report Run Date: 29-Jun-2021Data Lock Date: 08-Apr-2021 19:00:04Earliest Reaction Date: 14-Jan-1992MedDRA Version: MedDRA 23.1

Earliest Reaction Date. 14 Jan 1992		
Reaction Name	Total	Fatal
Vascular disorders		
Peripheral vascular disorders NEC		
Hot flush	2	0
Vascular disorders SOC TOTAL	2	0
TOTAL REACTIONS FOR DRUG	294	0
TOTAL REPORTS	90	
TOTAL REPORTS	90	